

**REMARKS**

Claims 1, 5, 6, 10, 11, 15, 16, 17, and 18 have been amended. Claims 19-23 have been added. Claims 3-4, 8-9, and 13-14 have been canceled without prejudice. No new matter has been added. Support for the amendments can be found throughout the original specification and specifically at line 25 of page 9 through line 25 of page 10 of the original specification. Claims 1-2, 5-7, 10-12, and 15-23 are presented for further examination.

**Objection to Drawings**

Applicants note that the Office has objected to drawings. The Office's attention is brought to the fact that the instant application was filed with no drawings and drawings were never added. The drawings the Office refers to were incorrectly placed in the Image File Wrapper of the present case. Although Applicants had nothing to do with the filing of the drawings or the placement in the IFW, Applicants believe the drawings were intended for U.S. Patent Application No. 10/806,693. Accordingly, Applicants respectfully request the withdrawal of the objection to the drawings.

**Claim Objections**

Claims 16 and 17 stand objected to for informalities. Applicants have corrected the informalities by the present amendment and respectfully request the withdrawal of the objection to the claims.

**Non-statutory Double Patenting Rejection**

Claims 1-18 stand rejected under a non-statutory obviousness-type double patenting based on claims 1-23 of U.S. Patent No. 6,627,613.

While Applicants respectfully disagree with the propriety of this rejection, in the interests of expedited examination Applicants have filed concurrently herewith a terminal disclaimer. Accordingly, Applicants respectfully request the withdrawal of the double patenting rejection.

**35 U.S.C. § 112, 1<sup>st</sup> Rejection**

Claims 1-15 stand rejected under 35 U.S.C. 112, 1st as failing to comply with the written description requirement.

The Office urges that the subject matter of claims 1-15 was not disclosed or supported in the original specification and claims of parent case, U.S. Patent Application No. 09/910,076, and therefore the subject matter of claims 1-15 constitutes new matter. Specifically, the Office finds that the limitation “without benzyl alcohol, N-methylpyrrolidone or 2-pyrrolodone” is not supported.

Although Applicants respectfully disagree with the Office’s position, in the

interests of expedited examination, Applicants have chosen to amend the claims to use “consisting essentially” language in place of the “without” language. Accordingly, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. 112, 1<sup>st</sup> paragraph.

**35 U.S.C. § 112, 2<sup>nd</sup> Rejection**

Claims 1-15 stand rejected under 35 U.S.C. 112, 2<sup>nd</sup> as being indefinite.

The Office finds the language “without benzyl alcohol, N-methylpyrrolidone or 2-pyrrolodone” to be unclear. Although Applicants respectfully disagree with the Office’s position, in the interests of expedited examination, Applicants have chosen to amend the claims to use “consisting essentially” language in place of the “without” language. Accordingly, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. 112, 2<sup>nd</sup> paragraph.

Claims 11-15 stand rejected under 35 U.S.C. 112, 2<sup>nd</sup> as being unclear. Although Applicants respectfully disagree with the Office’s position, in the interests of expedited examination, Applicants have chosen to amend the claims to use “consisting essentially” language in place of the “without” language. Thus, Applicants believe that the amount of the 50/50 propylene glycol/polysorbate 80 being added in the claims is clear. Accordingly, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. 112, 2<sup>nd</sup> paragraph.

Claim 16 stands rejected under 35 U.S.C. 112, 2<sup>nd</sup> as lacking proper antecedent basis. Applicants have amended this claim to provide proper antecedent basis and thus respectfully request the withdrawal of the rejection under 35 U.S.C. 112, 2<sup>nd</sup> paragraph.

**35 U.S.C. § 102 Rejections**

Claims 6-8 stand rejected under 35 U.S.C. 102(b) as being anticipated by Komer, U.S. Patent No. 5,773,422, ("Komer").

As amended, claim 6 recites a pharmaceutical solution *consisting essentially of* Ivermectin, 10-99% v/v isopropyl alcohol, propylene glycol and polysorbate 80 for the treatment of a broad spectrum of infestations caused by a parasite. Komer teaches a pharmaceutical solution of Ivermectin comprising either N-methylpyrrolidone or 2-pyrrolodone. Every example provided in Komer comprises either N-methylpyrrolidone or 2-pyrrolodone. Accordingly, Komer cannot anticipate the claimed invention which specifically excludes each of these essential ingredients from the pharmaceutical solution. Since N-methylpyrrolidone or 2-pyrrolodone are essential to the dissolution of Ivermectin in Komer, Komer cannot anticipate the claimed invention. Since Komer fails to anticipate claims 6-8, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. 102.

**35 U.S.C. § 103(a) Rejections**

Claims 1-8 and 10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Komer in view of Grosse-Bley et al., U.S. Patent No. 6,063,394, ("Grosse-Bley").

As stated above, each and every pharmaceutical solution disclosed by Komer includes either N-methylpyrrolidone or 2-pyrrolodone and thus fails to teach or suggest the claimed invention. Grosse-Bley fails to cure these deficiencies. Grosse-Bley teaches an Ivermectin solution comprising castor oil as the main solvent. Thus, castor oil is an essential component of the solutions taught by Grosse-Bley. The instant invention specifically restricts the pharmaceutical solution to the essential components of Ivermectin, 10-99% v/v ethyl alcohol (claim 1) or isopropyl alcohol (claim 6), propylene glycol, and polysorbate 80. Accordingly, the cited combination of Komer and Grosse-Bley fails to teach or suggest each and every limitation of the claims. Thus, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. 103 based on the combination of Komer and Grosse-Bley.

Claims 11-13 and 15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Komer.

Claim 11 requires that the pharmaceutical solution consists essentially of Ivermectin in an amount of 0.1-10% by weight of the solution, mixed with a solution of 50% propylene glycol and 50% polysorbate 80 by volume. As stated above, Komer only teaches pharmaceutical solutions using N-methylpyrrolidone

or 2-pyrrolodone as a primary solvent to dissolve Ivermectin. As such, Komer fails to teach or suggest the claimed invention which is limited to the claimed essential ingredients plus any compounds present in impurity level concentrations. Accordingly, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. 103 based on Komer.

Claims 1-15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Komer in view of Grosse-Bley and further in view of Lacy et al., U.S. Patent No. 5,645,856, ("Lacy").

As stated above, the combination of Komer and Grosse-Bley fails to teach the claimed invention since Komer relies on either N-methylpyrrolidone or 2-pyrrolodone as a primary solvent and Grosse-Bley relies on castor oil as a primary solvent, all of which are precluded from the claimed invention except at impurity level concentrations. Lacy fails to cure these deficiencies. Lacy teaches an Ivermectin carrier solution that uses a digestible oil as an essential component (see column 8, lines 45-46 of Lacy). Thus, the cited combination of Komer, Grosse-Bley, and Lacy fails to teach or suggest the claimed invention which limits the pharmaceutical solution to the essential components of Ivermectin, propylene glycol, and polysorbate 80 and optionally ethyl or isopropyl alcohol and optionally a flavoring agent. Accordingly, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. 103 based on the combination of Komer, Grosse-Bley, and Lacy.

**Newly Added Claims**

Claims 19-23 have been added by the present amendment. These claims are allowable for at least the reasons provided above with respect to claims 1-15.

**CONCLUSION**

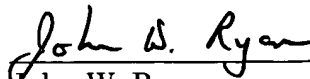
Applicants believe the present paper to be a complete and thorough response to the Non-Final Office Action. In view of the foregoing amendments and remarks, the application is respectfully submitted to be in condition for allowance. Accordingly, a timely favorable action is earnestly solicited.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #101918.56959C1).

Respectfully submitted,

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